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**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NO.

006420.00004

U.S. APPLICATION NO. (if known, See 37 CFR 1.5)

10/526285

PRIORITY DATE CLAIMED

2 September 2002

INTERNATIONAL APPLICATION NO.

PCT/IN2003/000294

INTERNATIONAL FILING DATE

2 September 2003

TITLE OF INVENTION

PHARMACEUTICAL COMPOSITION OF METAXALONE WITH ENHANCED ORAL BIOAVAILABILITY

APPLICANT(S) FOR DO/EO/US

DHARMADHIKARI, et al.

Applicant herewith submits to the United State Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)) (Unexecuted).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11-20 below concern other document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98.
12. ☐ An Assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☒ An Application Data Sheet under 37 C.F.R. 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 C.F.R. 1.821-1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:

International Search Report

International Publication WO 2004/019937 A1

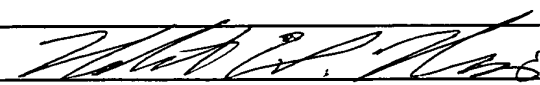
Chapter II Demand as filed with IPEA/AT

Written Opinion dated August 30, 2004

International Preliminary Examination Report

Forms PCT/IB/301, 304, 308, and 332

Five cited references

U.S. APPLICATION NO. (If known, See 37 CFR 1.51) <b>107526285</b>		INTERNATIONAL APPLICATION NO. PCT/IN2003/000294		ATTORNEY'S DOCKET NO. 006420.00004	
21. The following fees are submitted:					
<input checked="" type="checkbox"/>	a) Basic National Fee	\$300.00		\$300.00	
<input checked="" type="checkbox"/>	b) Examination Fee	\$200.00		\$200.00	
<input checked="" type="checkbox"/>	c) Search Fee	\$500.00		\$500.00	
<b>TOTAL OF ABOVE CALCULATIONS =</b>		<b>\$1,000.00</b>		<b>\$1,000.00</b>	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 500 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)		Rate	
- 100	/50			X \$250	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	20 -20 =	0	x \$50.00		
Independent Claims	2 - 3 =	1	x \$200.00		
Multiple dependent claims (if applicable)			+ \$360.00		
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$1,330.00</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated below above are reduced by 1/2.					
<b>SUBTOTAL =</b>				<b>\$1,330.00</b>	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).					
<b>TOTAL NATIONAL FEE =</b>				<b>\$1,330.00</b>	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property. +					
<b>TOTAL FEES ENCLOSED =</b>				<b>\$1,330.00</b>	
				Amount to be:	
				refunded	
				charged	
a. <input type="checkbox"/> A check in the amount of \$____ to cover the above fees is enclosed. b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. 19-0733 in the amount of <u>\$1,330.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0733. A duplicate copy of this sheet is enclosed.					
<b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status.</b>					
SEND ALL CORRESPONDENCE TO:					
<b>CUSTOMER NO.: 22908</b>			SIGNATURE		
BANNER & WITCOFF LTD.			ROBERT H. RESIS 32,168		
			NAME REG. NO.		
			March 2, 2005		
			DATE		

**TRANSMITTAL LETTER  
TO THE DO/EO/US**

Date	March 2, 2005
International Application No.	PCT/IN2003/000294
Attorney Docket No.	006420.00004

**10/526285**

**I. ☒ New Patent Application**

TITLE	PHARMACEUTICAL COMPOSITION OF METAXALONE WITH ENHANCED ORAL BIOAVAILABILITY
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Earliest priority date (Day/Month/Year)
2 September 2002

**SCREENING DISCLOSURE INFORMATION:** In order to assist in screening the accompanying international application for purposes of determining whether a license for foreign transmittal should and could be granted and for other purposes, the following information is supplied. (Note: check as many boxes as apply):

- A. ☐ The invention disclosed was not made in the United States.  
 B. ☐ There is no prior U.S. application relating to this invention.  
 C. ☒ The following prior application(s) contain subject matter which is related to the invention disclosed in the attached international application. (NOTE: *priority to these applications may or may not be claimed on form PCT/RO/101 (Request) and this listing does not constitute a claim for priority*)

application no.	790/MUM/2002	filed on	2 September 2002
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- D. ☐ The present international application ☐ is identical to ☐ contains less subject matter than that found in the prior U.S. application(s) identified in paragraph C above.  
 E. ☐ The present international application ☐ contains additional subject matter not found in the prior U.S. application(s) identified in paragraph C above. The additional subject matter ☐ **DOES NOT ALTER** ☐ **MIGHT BE CONSIDERED TO ALTER** the general nature of the invention in a manner which would require the U.S. application to have been made available for inspection by the appropriate defense agencies under 35 U.S.C. 181 and 37 CFR 5.1. See 37 CFR 5.15.

**II. ☐ A Response to the Invitation to Correct Defects from the RO/US.** The following document(s) is (are) enclosed:

- A. ☐  
 B. ☐ PCT Power of Attorney (General)  
 C. ☐ Replacement pages:


pages		of the request (PCT/RO/101)	pages		of the figures
pages		of the description	pages		of the abstract
pages		of the claims			

- D. ☐ Submission of Priority Document  
 E. ☐ Fees as specified on attached Fee Calculation sheet form PCT/RO/101 annex

**III. ☐ A Request for Rectification under PCT Rule 91      ☐ A Petition      ☐ A Sequence Listing Diskette**

- IV. ☒ Other (please identify):** Transmittal Letter to DO/EO/US Concerning a Filing under 35 USC 371  
 Preliminary Amendment  
 Application Data Sheet  
 (Unexecuted) Declaration and Power of Attorney  
 Information Disclosure Statement – Form PTO/SB/8A, with 3 references  
 International Publication WO 2004/019937 A1  
 International Search Report  
 Chapter II Demand filed with IPEA/AT  
 Written Opinion dated August 30, 2004  
 International Preliminary Examination Report  
 Forms PCT/IB/301, 304, 308, and 332  
 Certificate of Mailing - Return Postcard

The person signing this form is the: ☐ Applicant      ☐ Attorney/Agent (Reg. No. 32,168)      ☐ Common Representative

Typed name of signer	ROBERT H. RESIS	Signature	
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10/526285  
BT01 Rec'd PCT/PTT 02 MAR 2005

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Express Mail No. EV406110813US

Deposited March 2, 2005

I hereby certify that the attached correspondence, identified below, is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" under 37 CFR 1.10 on the date indicated above and is addressed to the: Mail Stop PCT, RO/US, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

By: 

(person actually depositing)

Applicant:	Sun Pharmaceutical Industries Limited
Attorney Docket No.:	006420.00004
Title:	Pharmaceutical Composition of Metaxalone with Enhanced Oral Bioavailability

1 sheet	PTO Form 1382
2 sheets	Transmittal Letter Concerning a Filing under 35USC371
5 sheets	Preliminary Amendment
4 sheets	Application Data Sheet
2 sheets	(Unexecuted) Declaration and Power of Attorney
1 sheet	Information Disclosure Statement
1 sheets	Form PTO/SB/8A, with 3 references
19 sheets	International Publication WO 2004/019937 A1
7 sheets	International Search Report
4 sheets	Chapter II Demand as filed with IPEA/AT
7 sheets	Written Opinion dated August 30, 2004
7 sheets	International Preliminary Examination Report
4 sheets	Forms PCT/IB/301, 304, 308, and 332
1 sheet	Certificate of Express Mailing
1	Return Postcard